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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/994,092	11/16/2001	David G. Charne	1271	7842
27310	7590	12/19/2003	EXAMINER	
PIONEER HI-BRED INTERNATIONAL INC. 7100 N.W. 62ND AVENUE P.O. BOX 1000 JOHNSTON, IA 50131			KRUSE, DAVID H	
			ART UNIT	PAPER NUMBER
			1638	

DATE MAILED: 12/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/994,092	CHARNE ET AL.
	Examiner David H Kruse	Art Unit 1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 25 September 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-56 is/are pending in the application.
- 4a) Of the above claim(s) 35-56 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-34 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) The translation of the foreign language provisional application has been received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). _____ .
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)
3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10/03. 6) Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, claims 1-34 in the response filed 25 September 2003 is acknowledged.
2. Claims 35-56 are withdrawn from further consideration pursuant to 37 CFR § 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the response filed 25 September 2003.
3. This application contains claim 35-56 drawn to an invention nonelected without traverse in the response filed 25 September 2003. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR § 1.144) See MPEP § 821.01.
4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR § 1.48(b) and by the fee required under 37 CFR § 1.17(i).

Priority

5. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Canada on 17 November 2000. It is noted, however, that applicant

has not filed a certified copy of the Canadian application as required by 35 U.S.C. § 119(b).

6. The incorporation of essential material in the specification by reference to a foreign application or patent, or to a publication is improper, see page 1 of the specification. Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. See *In re Hawkins*, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); *In re Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973).

7. In addition, any claim of priority is to appear in the first line of the specification.

Claim Objections

8. Claims 30-34 are objected to because of the following informalities: The phrase "A method" should read -- The method -- in referring to a previous method claim. Appropriate correction is required.

9. Claim 23 is objected to under 37 CFR § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 22 fails to further limit claim 22 to the extent that it reads on "self-pollination", "haploidy" and "single seed descent" because these breeding methods are not inherently directed to crossing with a

second *Brassica napus* plant. In addition, at line 1, the claim should be directed to further limiting -- the method of breeding -- at claim 22.

Claim Rejections - 35 USC § 101

10. 35 U.S.C. § 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

11. Claims 1-5 and 14-19 are rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter. Specifically the instant claims do not denote the hand of man, and thus are considered a product of nature. Amending the instant claims to be directed to an isolated cell or part of a *Brassica napus* plant would obviate this rejection.

Claim Rejections - 35 USC § 112

12. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

13. Claims 29-34 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 29 is indefinite because it is directed to a method comprising crossing a *Brassica napus* plant with a second *Brassica* plant of a different species, which would not produce a "hybrid canola seed" as claimed. Hence the metes and bounds of the claimed invention are unclear. Claims 30-34 are also indefinite because they do not obviate the indefiniteness of claim 29.

14. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

15. Claims 1-5, 7-11, 13-19, 21-27 and 29-33 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant claims plant cell of a *Brassica napus* plant which is Early Napus and resistant to at least one AHAS-inhibitor herbicide, a tissue culture of regenerable cells produced therefrom, a part of a *Brassica napus* plant which is Early Napus and resistant to at least one AHAS-inhibitor herbicide, and method of breeding using a *Brassica napus* plant which is Early Napus and resistant to at least one AHAS-inhibitor herbicide.

Applicant describes a *Brassica napus* variety NS3801, representative seed having been deposited under ATCC Accession No. PTA-2470, which is Early Napus and resistant to at least one AHAS-inhibitor herbicide.

Applicant does not describe the genus of *Brassica napus* plant which is Early Napus and resistant to at least one AHAS-inhibitor herbicide.

Hence, it is unclear that Applicant was in possession of the invention as broadly claimed. In the instant case, Applicant's description of a method of making *Brassica napus* variety NS3801 fails to adequately describe the claimed genus of *Brassica napus* plants which are Early Napus and resistant to at least one AHAS-inhibitor herbicide.

16. Claims 1-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant claims plant cell of a *Brassica napus* plant which is Early Napus and resistant to at least one AHAS-inhibitor herbicide, a tissue culture of regenerable cells produced therefrom, a part of a *Brassica napus* plant which is Early Napus and resistant to at least one AHAS-inhibitor herbicide, and method of breeding using a *Brassica napus* plant which is Early Napus and resistant to at least one AHAS-inhibitor herbicide.

Applicant teach a *Brassica napus* variety NS3801, representative seed having been deposited under ATCC Accession No. PTA-2470, which is Early Napus and resistant to at least one AHAS-inhibitor herbicide.

Applicant does not teach the genus of *Brassica napus* plant which is Early Napus and resistant to at least one AHAS-inhibitor herbicide.

The invention appears to employ novel plants. Since the plant is essential to the claimed invention it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the plant is not so obtainable or available, the requirements of 35 USC § 112 may be satisfied by a deposit of the plant. A deposit of 2500 seeds of each of the claimed embodiments is considered sufficient to ensure public availability. The specification does not disclose a repeatable process to obtain the plant and it is not apparent if the plant is readily

available to the public. It is noted that applicants have deposited the plant but there is no indication in the specification as to public availability or to the conditions under with which the deposit has been made. See claims 6, 12, 20, 28 and 34.

(a) If the deposit was made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of the patent., would satisfy the deposit requirement made herein (see 37 CFR § 1.808).

(b) If the deposit was not made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. §§ 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that

- (i) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
- (ii) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- (iii) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;

- (iv) a test of the viability of the biological material at the time of deposit (see 37 CFR § 1.807); and,
- (v) the deposit will be replaced if it should ever become inviable.

In re Wands, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) lists eight considerations for determining whether or not undue experimentation would be necessary to practice an invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

As directed to claims 1-5, 7-11, 13-19, 21-27 and 29-33, Applicant has failed to teach one of skill in the art how to make and use the inventions within the full scope of the claims. The limitation “resistance to at least one AHAS-inhibitor herbicide” is not a unique feature of the claimed invention, which Applicant admits to in the specification at pages 2-4. The limitation an “Early *Napus*” does not appear to be a predictable phenotype as defined by Applicant on page 4 of the specification, and could be interpreted as a relative phenotype depending upon which other *Brassica napus* varieties one of skill in the art compares such an “Early *Napus*” with. The art teaches that the exact locations or effects of loci involved in flowering times in *Brassica napus* are unknown, and thus the effects of their combination are unpredictable (Osborn *et al* 1997, Genetics 146:1123-1129, see page 1129, left column, 2nd paragraph). Hence, it would have required undue trial and error experimentation by one of skill in the art at the

time of Applicant's invention to make and use the genus of *Brassica napus* plants with resistance to at least one AHAS-inhibitor herbicide which is "Early Napus" as defined by Applicant, as broadly claimed.

Claim Rejections - 35 USC § 102/103

17. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

18. The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

19. Claim 1-5, 7-11, 13-19, 21-27 and 29-33 are rejected under 35 U.S.C. § 102(e) as anticipated by or in the alternative under 35 U.S.C. § 103(a) as being unpatentable over Patel (U.S. Patent 6,222,101, filed 24 February 1999).

Patel discloses a *Brassica napus* plant designated 45A51, which has an average maturity of 92 days (column 8, Table 1). It is noted that Applicant discloses the exemplified NS3801 *Brassica napus* variety as having an average maturity of approximately 102 days. Patel discloses that it is desirable to make said 45A51

Brassica napus plant variety resistant to imidazolinone or sulfonylurea herbicides by transformation with transgenes encoding mutant ALS and AHAS enzymes (column 16, lines 49-55). Patel discloses methods of using said 45A51 *Brassica napus* plant variety in methods of breeding by crossing with other inbred varieties of *Brassica napus* and tissue culture (columns 2-3; claims 6 and 7; claim 10).

Patel does not specifically teach the 45A51 *Brassica napus* plant variety that is resistant to at least one AHAS-inhibitor herbicide.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of Applicant's invention to use the teachings of Patel to make a 45A51 *Brassica napus* plant variety that is resistant to at least one AHAS-inhibitor herbicide be it an imidazolinone or a sulfonylurea. One of ordinary skill in the art would have had a reasonable expectation of success given the teachings of Patel (see claims 17-19).

Double Patenting

20. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

21. Claims 1-5, 7-11, 13-19, 21-27 and 29-33 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 7 and 12 of copending Application No. 09/993,751, PGPUB US 2002/013881 A1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed plant cell, plant part, tissue culture and methods of breeding of the instant specification would be considered obvious in view of the claimed NS3213 *Brassica napus* variety in the copending application. The NS3213 *Brassica napus* variety is taught as having at least one AHAS-inhibitor herbicide resistance (claim 1) and a maturity of approximately 98 days (Tables 3 and 4), and thus meet the limitations of the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

22. Claims 6, 12, 20, 28 and 34 are free of the prior art, which neither teaches nor fairly suggests the *Brassica napus* variety NS3801.
23. No claims are allowed.
24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (703) 306-4539, **(571) 272-0799 after 6 January 2004**. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (703) 306-3218, **(571) 272-0804 after 6 January 2004**. The fax telephone number for this Group is (703) 872-9306 Before Final or (703) 872-9307 After Final.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (703) 308-0196.



A handwritten signature in black ink, appearing to read "David H. Kruse" above "AU 1638".

David H. Kruse, Ph.D.
12 December 2003